

(19) World Intellectual Property Organization
International Bureau



(43) International Publication Date
18 December 2003 (18.12.2003)

PCT

(10) International Publication Number
WO 03/103760 A1

(51) International Patent Classification⁷: **A61M 15/06**

(21) International Application Number: **PCT/AU03/00710**

(22) International Filing Date: 6 June 2003 (06.06.2003)

(25) Filing Language: English

(26) Publication Language: English

(30) Priority Data:
PS 2863 7 June 2002 (07.06.2002) AU

(71) Applicants (for all designated States except US): **KABILA INVESTMENTS PTY. LIMITED** [AU/AU]; 174 Allan Street, Kyabram, Victoria 3620 (AU). **KERRIE LEE NOMINEES PTY. LIMITED** [AU/AU]; 18 Hayes Road, Strathmore, Victoria 3041 (AU).

(72) Inventor; and

(75) Inventor/Applicant (for US only): **COLLIE, Ian, James** [AU/AU]; 174 Allan Street, Kyabram, Victoria 3620 (AU).

(74) Agent: **A TATLOCK & ASSOCIATES**; 28 Drummond Street, Carlton South, Victoria 3053 (AU).

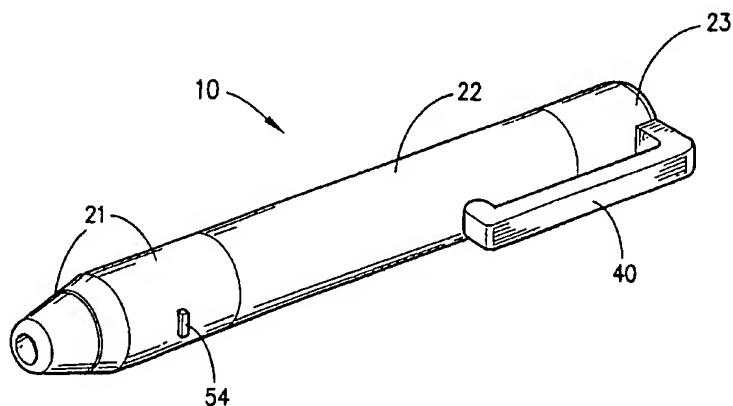
(81) Designated States (national): AE, AG, AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, BZ, CA, CH, CN, CO, CR, CU, CZ, DE, DK, DM, DZ, EC, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MA, MD, MG, MK, MN, MW, MX, MZ, NI, NO, NZ, OM, PH, PL, PT, RO, RU, SC, SD, SE, SG, SK, SL, TJ, TM, TN, TR, TT, TZ, UA, UG, US, UZ, VC, VN, YU, ZA, ZM, ZW.

(84) Designated States (regional): ARIPO patent (GH, GM, KE, LS, MW, MZ, SD, SL, SZ, TZ, UG, ZM, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, BG, CH, CY, CZ, DE, DK, EE, ES, FI, FR, GB, GR, HU, IE, IT, LU, MC, NL, PT, RO, SE, SI, SK, TR), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GQ, GW, ML, MR, NE, SN, TD, TG).

Published:
— with international search report

For two-letter codes and other abbreviations, refer to the "Guidance Notes on Codes and Abbreviations" appearing at the beginning of each regular issue of the PCT Gazette.

(54) Title: MEDICATION INHALER



WO 03/103760 A1

(57) Abstract: A medication inhaler device having a generally elongate pen shaped body (10) which includes a first (23) of the inhaler having external attachment means (40), a second component being a housing (22) for a medication canister, and a third component (21) being a housing for a discharged a terminal end of the inhaler.

MEDICATION INHALER

Area of the invention

This invention relates to the area of means for administering medication and in particular to the administration of medication in aerosol form and devices for delivering such medication.

Background to the invention

Medication for people such as asthmatics is customarily administered in aerosol form and may be either to prevent or relieve symptoms. Although other types of medication can be administered in aerosol form, for convenience sake devices for aerosol medication administration will be discussed here in terms of asthma treatment.

The existing form of aerosol dispenser is a metered-dose inhaler or "puffer" which consists of an aerosol unit and plastic mouthpiece. Unfortunately the metered dose can vary greatly depending on how such units are used.

Current inhalers can be hard to use for some in the community, such as the aged or frail who may have difficulty activating such devices as they do not have sufficient

-2-

strength to push the base of the inhaler to provide the correct amount of medication. In addition standard inhalers are relatively bulky and not easily readily carried in pockets and the like.

Another drawback associated with conventional inhalers is that people, whether children or adults, often do not want to be seen to be conspicuously using such devices

Outline of the invention

It is an object of this invention to provide a medication inhaler which is easily and inconspicuously carried by a patient and is simple to use when required as well as being able to be used discretely.

The invention is a medication inhaler device having a generally elongate pen shaped body which includes a first upper component of the inhaler having external attachment means, a second component being a housing for a medication canister and a third component being a housing for a discharge nozzle mechanism such that medication can be discharged through a terminal end of the inhaler.

It is preferred that these three components be able to engage with one and other and it is preferred that the engagement means be screw means.

It is further preferred that the means for holding the inhaler to the apparel be a lever device which when not in use acts as a clip to attach to a pocket or the like and also acts as a cocking means for the canister and causes pressure to be applied to it.

It is preferred that the canister have a metered dose valve which engages with the nozzle and, when actuated by being depressed, sprays a measured amount of medication.

In order that the invention may be more readily understood we will describe by way of non limiting example a specific embodiment of the invention with reference to the accompanying drawings.

Brief Description of the Drawing Figures

- Fig. 1 shows a perspective view of the inhaler of the invention;
- Fig. 2 shows an exploded view of the components of the invention;
- Fig.3 shows a view of the interior of the inhaler;
- Fig. 4 shows the dispensing mechanism of the inhaler and the dispensing mechanism components;

Description of a Preferred Embodiment of the Invention

In a preferred embodiment of the invention an elongate pen shaped medication dispensing inhaler 10 is provided which has a body housing 20 which consists basically of 3 components which can be screwed together as shown in Figure 2.

A forward portion 21 holds a nozzle type dispensing mechanism while a central portion 22 acts as a housing for the medication holding canister and attachable to this is a housing 23 for a cocking mechanism to actuate the medication canister 30 to prepare the inhaler prior to discharge a dose of the medication.

The cocking mechanism includes a lever 40, a cam follower 41, a plunger 42 and a return spring 43. The lever 40 has a dual function in that it can be used to connect the inhaler to a pocket, in the same manner as a standard pen is attached to a pocket. When the lever is rotated through approximately 90 degrees its end 44 which is internal to the inhaler acts as a cam and applies pressure to the cam follower 41 which slides inside the inhaler.

The plunger 42 also slides within the inhaler and is sprung within the cam follower 41. When the lever 40 is rotated as described its cam action acts against the cam follower which compresses the spring and causes the plunger to press against the top of the canister 31.

The canister 30 which holds the medication has a metered dose valve which, when activated can spray a measured amount of medication to the delivery nozzle 50.

The canister 30 has an outlet tube 32 which is inserted into the delivery nozzle 50 and is in fixed relationship with it. When the canister is pressed down relative to the outlet tube the metered dose valve acts to discharge a metered dose of medication through the nozzle. The arrangement is that pressure is applied to the canister by cocking the

lever and that depression of the actuator 54 extending through the nozzle housing permits movement of the canister towards the delivery end 60 of the inhaler and relative to the outlet tube 32 thereby causing the medication to be discharged into the nozzle.

The components of the nozzle assembly are shown in Figure 4 and include nozzle 50 (Figure 3), nozzle support 52, actuator 54, pawl 55 and canister support 56.

When the canister is cocked the canister leading edge presses against the canister support. This support in turn bears on the pawl which has two legs which rest on a step in a slot in the nozzle support 52. When the actuator 54 is depressed it deflects the legs of the pawl away from the step, which allows the pawl to slide in the direction of end 60 of the inhaler.

This movement allows the canister support 56 and canister 30 to move in the direction of end 60. As this movement of the canister is relative to the stationery delivery tube 32 the delivery of a metered dose of medication into the nozzle is effected.

When the actuator is released the legs of the pawl are straightened. When the lever 40 is rotated back to its "clip" position the canister lift spring 51 returns the canister, the canister support and pawl to their rest positions prior to being used for another dose.

It is envisaged that in the inhaler of the invention multi dose canisters can be used and that these canisters can easily be replaced as required by unscrewing the components of the inhaler and replacing the canister in its housing.

The means of interconnection of the inhaler components is not restricted in this invention and it is envisaged that in another embodiment of the invention the nozzle and canister housing components could be unitary. Indeed the housing for the cocking mechanism could be unitary with the canister housing. Alternatively if the inhaler of the invention was designed to deliver one dose only the entire inhaler housing could be an integral unit.

By means of this slim line inhaler of the invention a user can discretely insert the nozzle end of the inhaler "pen" into their mouth and press the actuator button thereby delivering the medication and inhale it in a simple action.

There are many advantages to the inhaler of the invention one of which is the way that the inhaler can sit in a person's pocket utilising the pen type clip such that it has the appearance of a conventional pen. This makes it both convenient and discrete to carry.

In addition the inhaler device is light weight and particularly easy to use. It is also envisaged that refills for the inhalers would be readily available at selected retail outlets.

Although this invention is particularly useful in relation to the administration of asthma medication it is envisaged that any medications which are required to be delivered in an aerosol form could be used in the inhaler of the invention.

While we have described herein a specific embodiment of the invention it is to be understood that variations in and modifications thereof may be made without departing from the scope of the invention.

Variations in the dimensions of the components, for example the size of whatever container is used, or variations in the shape and configuration of the components and materials from which they are made would all lie within the scope of the invention provided it is substantially slim line and light weight.

The claims defining the invention are as follows:

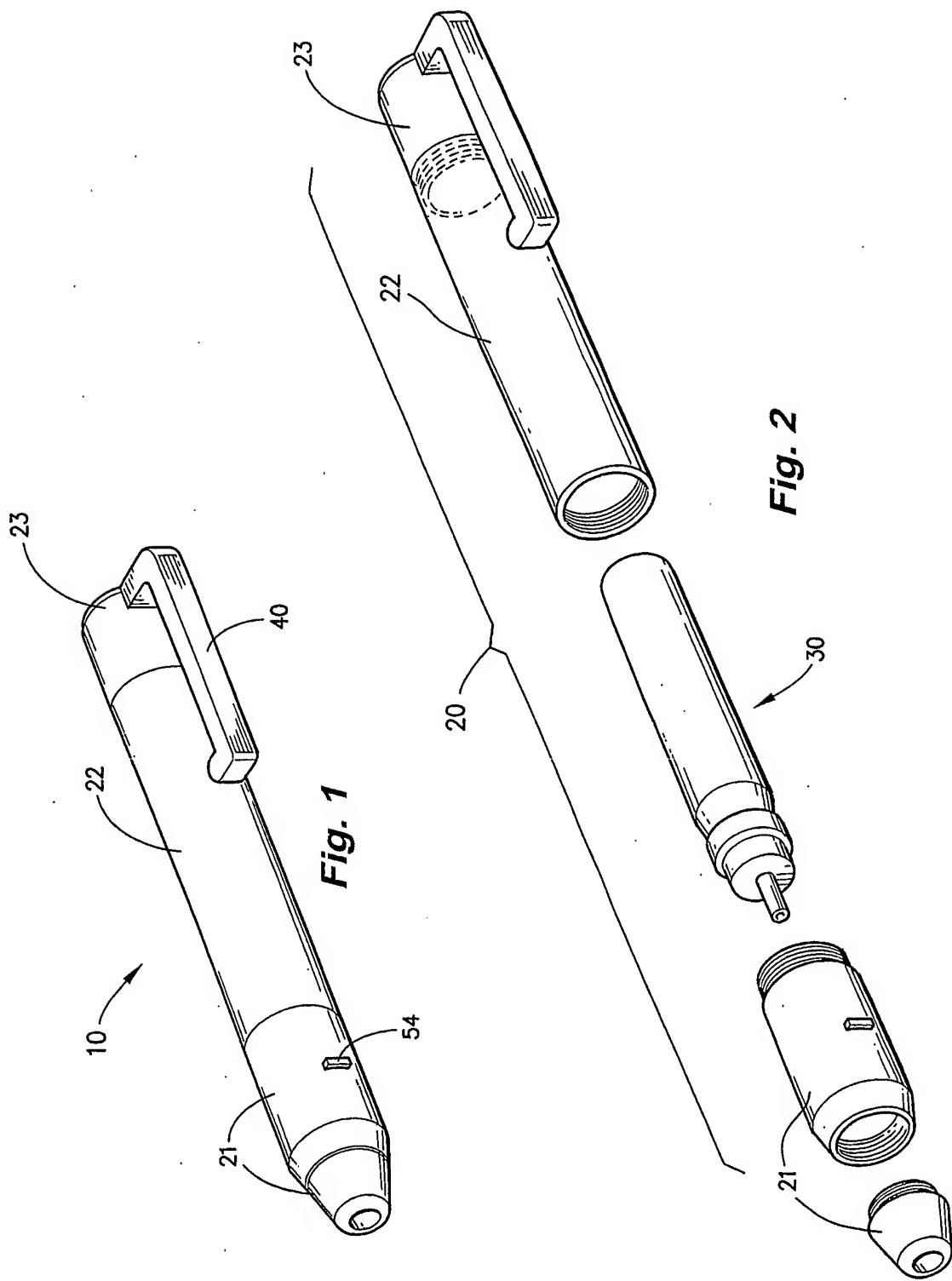
1. A medication inhaler device having a generally elongate pen shaped body which includes a first upper component of the inhaler having external attachment means, a second component being a housing for a medication canister and a third component being a housing for a discharge nozzle mechanism such that medication can be discharged through a terminal end of the inhaler.
2. A medication inhaler device as claimed in claim 1 wherein the three components are adapted to engage with one another.
3. A medication inhaler device as claimed in claim 2 wherein the components are in screw engagement
4. A medication inhaler device as claimed in claim 1 wherein the attachment means is a lever device which can hold the inhaler to apparel when not in use and otherwise acts as a cocking means for the canister and causes pressure to be applied to it when the lever is raised to be generally orthogonal to the axis of the inhaler.
5. A medication inhaler device as claimed in claim 4 wherein the lever passes through the first component housing and has a terminal end therein in camming relationship with a cam follower which is caused to act upon and apply pressure to the canister when the lever is raised.

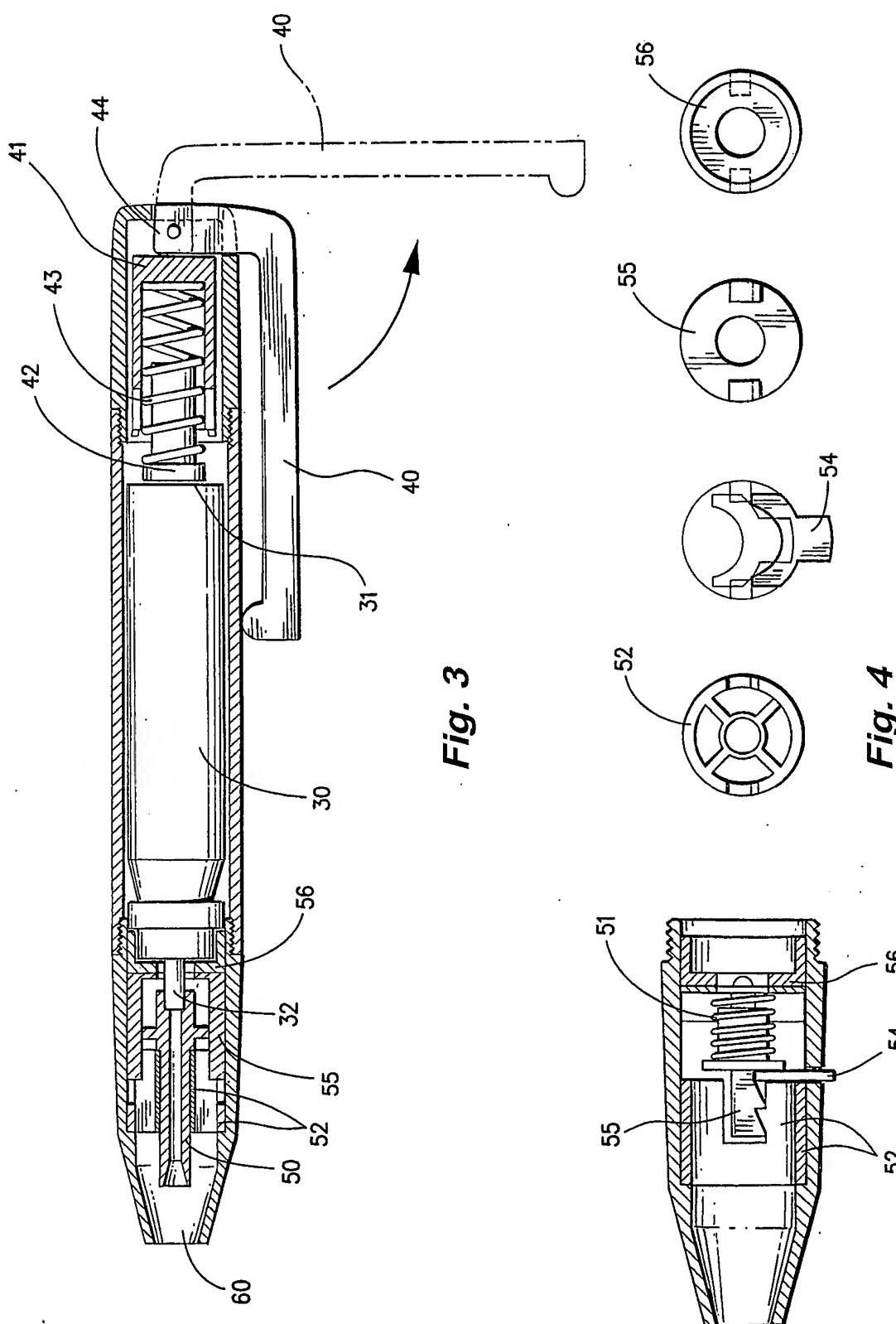
6. A medication inhaler device as claimed in claim 5 wherein the canister has a metered dose valve associated with a canister outlet tube which is mounted in the third component in stationery relationship with the nozzle such that movement of the canister towards the nozzle end of the inhaler causes a measured amount of medication to be sprayed into the nozzle.
7. A medication inhaler device as claimed in claim 6 wherein movement of the canister towards the nozzle end of the inhaler is effected by means of an actuator which deflects restraining means in the third housing component which would otherwise prevent canister movement in this direction.
8. A medication inhaler device as claimed in claim 7 wherein the actuator consists in part of a button mechanism extending through the third component housing to the exterior of the inhaler.
9. A medication inhaler device wherein the actuator has an arcuate shape inside the inhaler such that when it is depressed into the inhaler it deflects two arms associated with a pawl thereby permitting it and the canister to move in the direction of the terminal end of the inhaler and causing the metered dose valve to spray the medication into the nozzle.
10. A medication inhaler device wherein return of the lever to its clip position permits the canister and pawl to return to their positions prior to use.

-10-

11. A medication inhaler device substantially as herein described with reference to the accompanying drawings.

1/2





INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00710

A. CLASSIFICATION OF SUBJECT MATTER

Int. Cl. 7: A61M 15/06

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

DWPI+keywords: inhaler puffer separate distinct screw clip lever canister reservoir slim pen elongate and similar terms

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	RU 2158573 C2 (GLAVNYJ VOENNYJ KLINICHESKIJ GOSPITAL'IM et al) 10 November 2000	1-2
A	English abstract and figures	3-8
A	English abstract and figures	
A	EP 925799 A2 (PY) 30 June 1999	1-8
	Whole document	
A	GB 2316451 A (TENAX CORP) 25 February 1998	1-8
	Whole document	

 Further documents are listed in the continuation of Box C See patent family annex

* Special categories of cited documents:	
"A" document defining the general state of the art which is not considered to be of particular relevance	"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
"E" earlier application or patent but published on or after the international filing date	"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)	"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
"O" document referring to an oral disclosure, use, exhibition or other means	"&" document member of the same patent family
"P" document published prior to the international filing date but later than the priority date claimed	

Date of the actual completion of the international search
11 August 2003

Date of mailing of the international search report

13 AUG 2003

Name and mailing address of the ISA/AU
AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

Sue Thomas

Telephone No : (02) 6283 2454

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00710

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	GB 2292891 A (NORTON HEALTHCARE LTD) 13 March 1996 Pages 16-18, figures 5A-5C	1-8
A	WO 94/04209 A1 (MINNESOTA MINING AND MANUFACTURING CO) 3 March 1994	1-8
A	WO 02/30503 A1 (ASTRAZENECA AB) 18 April 2002	1-8

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU03/00710

Box I Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. Claims Nos :
because they relate to subject matter not required to be searched by this Authority, namely:

2. Claims Nos :
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically:

3. Claims Nos :
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a)

Box II Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

Claims 1-8 Medication inhaler, having pen shape and external, upper component attachment means
 Claim 9 Medication inhaler having actuator of arcuate shape which, when depressed, deflects two arms associated with a pawl
 Claim 10 Medication inhaler having lever which has return clip position allowing canister and pawl to locate in positions held prior to use.

1. As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims
2. As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claims Nos.:

4. No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:1-8

Remark on Protest

The additional search fees were accompanied by the applicant's protest.
 No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No.

PCT/AU03/00710

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report				Patent Family Member			
EP	2292891	GB	9418064				
GB	2316451	AU	39480/97	EP	918570	PL	331613
		US	6109479	ZA	9707185		
EP	925799	AU	97164/98	JP	11267225	US	6033384
WO	02/30503	AU	200196110	EP	1326667	SE	200003665
WO	94/04209	AU	47282193	EP	660731	NZ	254959
		US	5511540				
RU	2158573	NIL		END OF ANNEX			